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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/664,575	09/17/2003	Jonathan Fanger	101896-0208	3611
21125 7590 04/03/2009 NUTTER MCCLENNEN & FISH LLP WORLD TRADE CENTER WEST 155 SEAPORT BOULEVARD BOSTON, MA 02210-2604			EXAMINER SWIGER III, JAMES L.	
			ART UNIT 3775	PAPER NUMBER
			NOTIFICATION DATE 04/03/2009	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

doctet@nutter.com

Office Action Summary

Application No.

10/664,575

Applicant(s)

FANGER ET AL.

Examiner

JAMES L. SWIGER

Art Unit

3775

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 December 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3, 7, 11, 12, 16, 17, 25-28, 52-58, 61 and 62 is/are pending in the application.
- 4a) Of the above claim(s) 11, 12 and 26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 7, 16, 17, 25, 27, 28, 52-58, 61 and 62 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 3/3/2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3, 7, 16-17, 25, 27-28, 52-55, 57-58, 61-62 are rejected under 35 U.S.C. 102(b) as being anticipated by Coates et al. (US Patent 5,423,826) hereafter Coates.

Coates discloses a guide device for use with a spinal plate comprising an elongate shaft (151/152) having a proximal (end @150) and distal ends (opposite), a guide member (157) coupled to the distal end of the elongate shaft, including first and second lumens (see 158 and opposing side in Fig. 14), extending therethrough in fixed relation to one another (in one manner, they may be in fixed relation via the adjustment knob), wherein the first and second lumens have central axes that extend in a plane parallel to opposed superior and inferior surfaces of the guide member (see annotated drawing below). The central axes are those of the guide members and the superior/inferior surfaces are shown with solid lines.

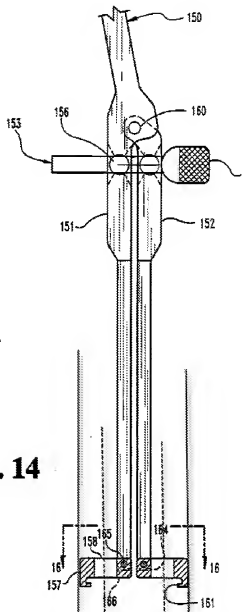


Fig. 14

Coates further discloses first and second opposed alignment tabs (159/161) that extend distally from opposed superior and inferior surfaces of the guide member, and wherein these alignment tabs are able to non-fixedly interact with a spinal plate (see fig. 19 with plate (22)) or with an edge of a spinal plate and the guide members have the ability to flex with respect to one another, and they also prevent rotation between the

guide device and the plate. It is noted that the guide members align with the screw holes of a plate (see fig. 19). Coates further discloses at least one protrusion (170) that extends from the guide member through to the plate and is disposed within a corresponding bore. See also Fig. 19. The guide member is considered to have a shape that conforms to the shape of a spinal plate (Fig. 19 shows no/ a minimum gap between the guide member and the plate). The first and second lumens are considered to be at an angle with one another, and in terms of the above fig. 14, zero or 180 degrees are considered angles with respect to one another.

Claims 52, 54-55, 57-58, 61-62 are rejected under 35 U.S.C. 102(e) as being anticipated by Null et al. (US Patent 7,011,665), hereafter "Null."

Null discloses a guide device for use with a spinal plate having an elongate shaft (10, Fig. 3), having a proximal and distal ends that are at an angle with respect to one another, a guide member (30/31) coupled to the distal end of the shaft having first and second lumens (30/31) that are in a fixed relation to one another, that further have central axes (95/96) that are parallel to opposed superior and inferior surfaces of a the guide member (see drawing below).

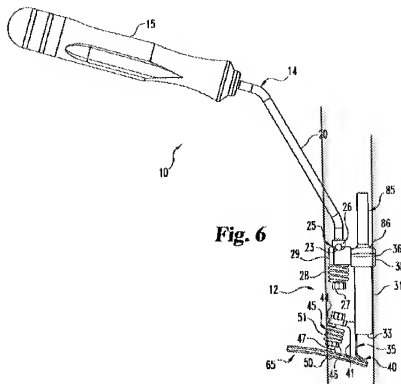


Fig. 6

Null further discloses at least one alignment tab (35/40) that extends distally from one of the superior or inferior surfaces (note the inner end not annotated can also be one of the superior or inferior surfaces for illustrative purposes, which would still be parallel to a lumen axis), which is adapted to interact with a spinal plate to position a guide member and a corresponding pair of screw holes (see fig. 7), and further has at least one protrusion (47/50) which extends distally from the guide member and is adapted to be disposed within a corresponding bore (80) of the plate. It is noted that the guide member's open shape conforms to the shape of the plate, or, alternatively, the springed portion of the protrusion has the ability to conform to the shape of the plate.

Claims 1 and 52 are rejected under 35 U.S.C. 102(e) as being anticipated by Foley (US Publication 2004/0092947).

Foley discloses a device for use with a spinal plate having an elongate shaft (24) wherein the proximal and distal (end towards the spinal plate) ends are angled in relation to one another, further having a guide member (25) coupled to the distal end having first (26) and second (66) lumens extending therethrough in fixed relation (41), to one another, where the first and second lumens have central axes that extend in a plane that is parallel to opposed superior and inferior surfaces of the guide member. See drawing below. The solid lines are superior/inferior surfaces.

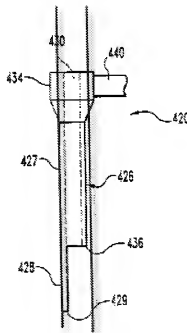
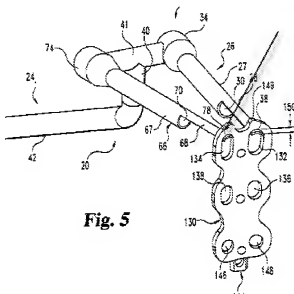


Fig. 9

Foley further disclose first and second opposed alignment tabs (28/68), that are adapted to interact with a spinal plate. In an alternative interpretation Foley has at least one alignment tab that is adapted to interact with a spinal plate, wherein the other tab as

mentioned is considered at least one protrusion that extends distally and is adapted to be disposed within a corresponding bore formed in a spinal plate.



Claim Rejections - 35 USC § 103

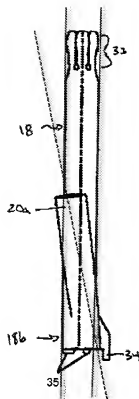
The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 56 is rejected under 35 U.S.C. 103(a) as being unpatentable over Coates '826. Coates discloses the claimed invention except for protrusions having specifically an oval shape. It would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to construct the protrusions having an oval shape, since applicant has not disclosed that such solve any stated problem or is anything more than one of numerous shapes or configurations a person ordinary skill in

the art would find obvious for the purpose of fitting tightly in a receiving bore of a plate to prevent unwanted movement. In re Dailey and Eilers, 149 USPQ 47 (1966).

Claim 52 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kolb et al. (US Patent 6,960,216). Kolb et al. disclose a guide device for use with a spinal plate having an elongate shaft (30a), having a proximal (@ approx 33) and distal ends (@ approx 30b) and a guide member coupled to the distal end (20a/20b) which has a first and second lumens extending therethrough. These lumens have central axes. Kolb also discloses at least one alignment tab (34) that is adapted to interact with a spinal plate and also protrusions (35), which are designed to fit into a corresponding bore in the plate (or detent). Kolb disclose the claimed invention except for wherein the central axes of the lumens are considered parallel to axes defined by the superior and inferior portions of the guide device. As shown below, the superior and inferior portions are in solid lines, and the central axes is dotted.



It is however noted that Kolb also teaches that the respective axes of the barrels or lumens can vary between zero and 15 degrees from this center measurement point of the elongate shaft (see Fig. 4). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Kolb having inclined axis of the guide device to the axis of the elongate shaft, as Kolb contemplates that there may be variation in plate design or surgical needs to insert screws and access the holes in a plate (Fig. 7) in a certain way.

Response to Arguments

Applicant's arguments with respect to claims 1, 3, 7, 16-17, 25, 27-28, 52-58, 61-62 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **JAMES L. SWIGER** whose telephone number is (571)272-5557. The examiner can normally be reached on **M-F, 9am-5:30pm**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JAMES L. SWIGER/
Examiner, Art Unit 3775

/Eduardo C. Robert/
Supervisory Patent Examiner, Art Unit 3733